DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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PDB 11/27/96

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

Certified/Return Receipt Requested

November 25, 1996

WARNING LETTER

Kurt E. Johnson, Chief Executive Officer
Hammer, Inc.
600 East Grand Avenue
Des Moines, Iowa 50309

Ref. # - KAN-97-03

Dear Mr. Johnson:

During an inspection of your compressed medical oxygen transfilling operation known as Hammer Medical Supply, 1775 N.W. 86th, Clive, Iowa, conducted on October 17 to 21, 1996, a Food and Drug Administration Investigator from this office documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211) which cause your firm's medical oxygen to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Significant deviations to 21 CFR, Part 211 include, but are not limited to the following:

failure to perform quality assurance reviews of production and control records to ensure that compressed medical oxygen was manufactured in accordance with established procedures [21 CFR 211.22];

failure to properly calibrate the : Oxygen Analyzer used for the assay of Oxygen, USP, in that your firm is not following the established procedures or operators manual, and you are using an expired cylinder of oxygen which is used for calibration [21 CFR 211.160(b)(4)];

failure to establish written procedures and maintain records for the calibration of equipment used in the filling of compressed medical oxygen [21 CFR 211.68(a)];

failure to follow written procedures designed to assure that correct labels are used for the cylinders of compressed medical oxygen you manufacture, in that the labels of some filled cylinders did not contain your address, some

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cylinders had no labels for your firm on them, some cylinders had the original labeling on them from another firm, and some cylinders had improper or old lot numbers on them [21 CFR 211.130].

At the conclusion of the inspection Form FDA 483, List of Inspectional Observations, was prepared, issued to and discussed with you. This is a comprehensive list of deviations observed by the investigator during the inspection.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action <u>without further notice</u>. Such actions may include seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps, that are being taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District